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10/602,544

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Li-fang Liang

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EXAMINER

LONG, SCOTT

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/602,544	Applicant(s) LIANG, LI-FANG	
	Examiner SCOTT D. LONG	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5 is/are allowed.
- 6) ☒ Claim(s) 6-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 10 December 2007.

Claim Status

Claims 1-15 are pending. Claims 1, 6 and 11 are amended. Claims 1-15 are under current examination.

Priority

This application claims benefit as a CON of 09/632,879 (filed 08/04/2000 ABN) which is a DIV of 09/354,409 (filed 07/15/1999, issued PAT 6,555,672) which claims benefit of 60/092,865 (filed 07/15/1998) and claims benefit of 60/123,270 (filed 03/08/1999). The instant application has been granted the benefit date, 15 July 1998, from the application 60/092,865.

Response to Arguments - Claim Objections

Applicant's arguments, see page 5 and Claim amendments, filed 10 December 2007, with respect to claims 1, 6 and 11 have been fully considered and are persuasive. The objections to claims 1, 6 and 11 have been made moot by the claim amendments submitted on December 2007 and are hereby withdrawn.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – 35 USC 112, second paragraph

Applicant's arguments, see page 5 and Claim amendments, filed 10 December 2007, with respect to rejection of claims 1-15 for "omitting essential steps" have been fully considered and are persuasive. The rejections of Claims 1-15 under 35 USC 112, second paragraph, have been made moot by the claim amendments submitted on 10 December 2007 and are hereby withdrawn.

Response to Arguments – Written Description (35 USC 112, first paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's arguments and claim amendments filed 10 December 2007 have been fully considered but they are unpersuasive. Claims 6-15 remain rejected under 35 USC 112, 1st paragraph (written description) for the reasons of record and the comments below.

The examiner apologizes for misquoting the instant claims by asserting that the claims were directed to a genus of promoters comprising isolated nucleic acids which are at least 90% identical to SEQ ID NO: 1, when in fact the independent claims are

directed to a genus of promoters comprising isolated nucleic acids which are at least 95% identical to SEQ ID NO: 1.

The applicant's arguments are as follows:

According to the Written Description Guidelines, "variants of a protein that are at least 95% identical to a particularly disclosed sequence and that have a particularly specified activity in combination with an accompanying specification that discloses a single species falling within the claimed genus, satisfies the requirements of 35 USC 112, first paragraph, for written description."

The examiner disagrees with the applicant's assertion that the instant claims satisfy the written description guidelines as cited above. There are similarities between the example and the instant claims, namely, that the applicant has indirectly recited that SEQ ID NO: 1 has a specified activity (i.e., gene regulatory activity), "such that the gene is transcribed and expressed." However, the example cited is directed to a protein, while the instant claims are directed to a promoter. The examiner believes this to be an important distinction that separates the instant claims from the example cited in the Written Description Guidelines. Since it is not as clear which portions of a promoter can be modified to produce a functional variant as it might be with a conservative substitution of a protein, the examiner believes it is incumbent upon the specification to identify which portions of the promoter are critical for its activity. Because the specification does not indicate the critical control elements within SEQ ID NO: 1, the examiner believes the specification lacks written description for the claimed genus.

Therefore, the rejection of claims 6-15 under 35 USC 112, first paragraph (written description) is hereby maintained.

Response to Arguments – Scope of Enablement (35 USC 112, 1st paragraph)

Applicant's arguments and claim amendments filed 10 December 2007, directed to rejection of claims 1-15 remain under 35 USC 112, 1st paragraph (scope of enablement) have been fully considered and they are persuasive.

The applicant argues that the instant claims are directed to “cultured cell[s]” and therefore cannot apply to *in vivo* methods. The examiner finds this argument persuasive.

Therefore, the rejection of claims 1-15 under 35 USC 112, first paragraph (written description) is hereby withdrawn.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Claim 11 is directed to a method of identifying a compound which regulates GDF-8 expression comprising operably linking to a gene "a portion of an isolated GDF-8 promoter comprising the nucleotide sequence SEQ ID NO: 1, 2, or 3." Example 4 (page 16) in the specification describes construction of luciferase expression plasmids containing a minimal promoter sequence (pGL2-0.21 containing the region -1 to -207) and one or more copies (concatamers) of SEQ ID NO:2 or 3. The specification indicates expression of the luciferase reporter constructs comprising concatamers of SEQ ID NO: 2 "was dependent on the number of copies of this sequence contained within the construct", while concatamers of SEQ ID NO: 3 were 100% of the control regardless of the number of copies. According to these teachings, the difference in expression of the gene compared to control is not always due to the presence of a "screened" compound, but may be due to the particular promoter (e.g. - concatamers of SEQ ID NO:2). Furthermore, since concatamers of SEQ ID NO: 2 are required for expression and the number of copies shown to function in the assay is 10 copies, the examiner believes the scope of the claim 11 is not adequately described. In addition, the specification indicates that besides concatamers of SEQ ID NOs: 2 or 3, the screening construct

requires a minimal promoter sequence containing the region -1 to -207. The claims do not reflect this requirement. Therefore, the instant claim language is new matter.

Allowable Subject Matter

Claims 1-5 are allowed. The following is a statement of reasons for the indication of allowable subject matter: United States Patent US-6399312 is the closest related art, but does not qualify as prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-5 are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long
Patent Examiner
Art Unit 1633

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633